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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,365	01/31/2001	Suman Khowala	8920-000005	3998

7590 10/06/2003

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/773,365	KHOWALA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 6-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/03 has been entered.

Claims 3 and 6-18 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 6-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the range of 10 µg/ml to about 2 mg/ml for any glycosylation inhibitor as now recited in claim 3. With respect to the results reported, there is no basis or support in the written disclosure as-filed for the production of an enzyme preparation containing cellobiase activity that is increased "at least about 1.15 fold to about 97-fold" increase in cellobiase activity. There is no basis for the "at least" terminology, and it is unclear what is intended. See also the rejections under 35 U.S.C § *infra*. In addition, the conditions under which the reported results are obtained are not stated and do not necessarily correspond to the present invention. No side-by-side comparison is provided in the present record regarding the effects of any strain of *Termitomyces clypeatus* and of any glycosylation inhibitor.

No basis or support is found in the present specification for the "at least" values for cellobiase activity as indicated in claims 13-18. Similarly, no basis for support is found for the "at least" values regarding the glycosylation inhibitors in claims 17 and 18.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 6-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite in that the nature of “control culture” in this context is unclear. There is no clear indication of what constitutes a “control” in the context of the present invention. In Table 3 for example, there are no “controls”. The conditions under which the reported results are obtained are not stated and do not necessarily correspond to the present invention. No side-by-side comparison is provided in the present record regarding the effects of any strain of *Termitomyces clypeatus*.

Claim 3 is vague indefinite and confusing in the recitation of production of an enzyme preparation containing cellobiase activity that is increased “at least about 1.15 fold to about 97-fold” increase in cellobiase activity, since the intended object of “at least” is at least ambiguous. Is it “at least about 1.15 fold” or is it “at least about 97 fold”? It cannot be both. Moreover, if it is “at least about 1.15 fold” then the range is infinite and should not end at “about 97 fold”. As noted *supra*, this material constitutes new matter.

In addition, claim 3 appears incomplete and inconsistent as written. Dependent claim 6 suggests that the medium of claim 3 lacks assimilable carbon and nitrogen sources as well as inorganic salts and organic nutrients. It is unlikely that the cells would “grow” in the absence of these indispensable nutrients. Therefore, the material of claim 6 should be incorporated into claim 3 to complete the claimed process.

Claims 12-18 fail to find proper antecedent basis in claim 3 for “high” cellobiase activity.

Claims 17 and 18 fail to find proper antecedent basis in claim 3 on which they ultimately depend for the recitation of “at least” with respect to the glycosylation inhibitor recited, as well as in the specification as filed, as noted in the new matter rejection, *supra*.

Applicants’ arguments regarding the rejection under 35 U.S.C 103 are persuasive and the rejection is withdrawn.

No claim is allowed.

The claims would be allowable upon resolution of all issues under 35 U.S.C § 112.

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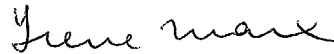
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner
Art Unit 1651